



# **Yorkshire Cancer Research Network**

## **Annual Report**

### **April 2004 – March 2005**

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**June 2005**

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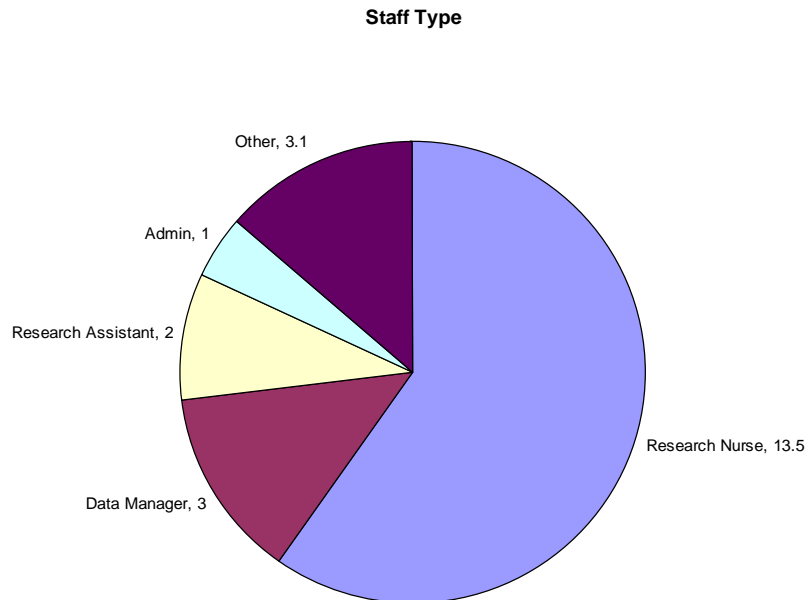
## 1. Organisation and Development of Network

### 1.1 Overview and Development of Network

The YCRN was one of the second wave of NCRN Networks and was designated in October 2001. Our Strategic Outline Plan was agreed by the Host Institution and signed off by NCRN and DoH in March 2002. Core staff were appointed during 2002 and early 2003. Additional clinical research staff were appointed throughout 2003/04. Staff in post are detailed in Appendix 1.1

The YCRN funds 22.6 whole time equivalent (w.t.e.) staff across the Network. This is a total of 28 individuals, all of who directly support the set up and accrual for NCRN portfolio trials. The YCRN also financially supports a further 3 posts in hospital service departments which indirectly support NCRN activity.

The pie chart below shows the proportion, in terms of types of posts held, of appointments currently funded by the YCRN



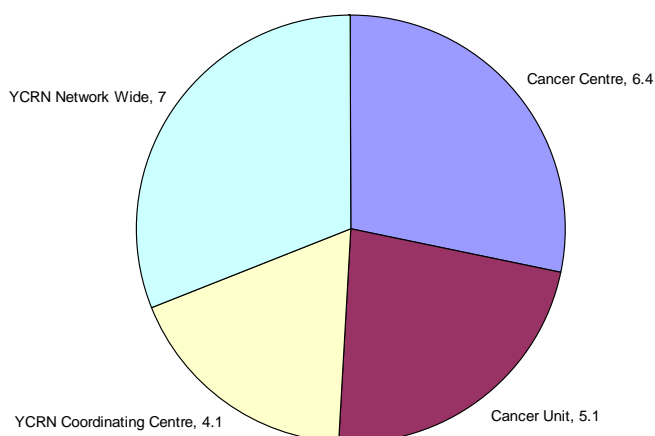
The second pie chart (overleaf) details the proportion of funded staff in the cancer centre, cancer units, YCRN Network wide and the YCRN Coordinating Centre.

Of the 22.6 wte staff, 13.5 are research nurses. This is the largest group of individuals employed by the YCRN and continues to reflect the ratio of nurses to other research staff across the whole Network. The remainder of staff groups comprise Data Managers (3 w.t.e.), Research Assistants (2 w.t.e.), Administrator (1 w.t.e.), Education & Information Manager (1 w.t.e.), IT Manager (1 w.t.e.), Network Manager (1 w.t.e.) and Research Clinical Lead (0.1 w.t.e.).

In addition to these 22.6 w.t.e. posts, three additional NHS posts receive some financial support from YCRN. These include a Therapy Radiographer, a Pharmacy Technician and a Pathology Technician. Funding for these three posts was initially agreed for three years; this is up for review during 2005/06.

The staffing profile has changed very little over the last year. Of the 13.5 w.t.e. research nurses, 10.5 w.t.e. have traditional roles, actively recruiting patients into clinical studies across a range of clinical trials with varying degrees of cancer site-specialisation and performing trial data capture. 9.5 w.t.e. of these posts are based predominantly at a single hospital site. 1 w.t.e. Research Nurse works across several Cancer Units supporting haematology trial activity.

YCRN Funded Staff, Network Placement



3 w.t.e. Research Nurses and the 3 w.t.e. Data Managers act as portfolio coordinators for the whole Network, working with hospital site-based staff to improve clinical trials activity. Their current portfolios include colorectal, breast, lung, upper GI, urology, gynaecology, haematology, sarcoma, skin, head & neck, palliative and primary care. The remit of these individuals is to assist and lead the development of Network wide portfolios by promoting, educating, trouble shooting, supporting and completing regulatory paper work i.e. Ethics Committee and R&D applications.

2 w.t.e. Research Assistant posts were created to promote new trials activity in specific areas of the NCRN portfolio. The first of these is in psychosocial oncology, reflecting a major interest and activity within the Yorkshire Network. The second, recently developed, will support the NCRN screening and genetics portfolio.

As last year's report states, all the Trusts in the Network now have locally employed staff funded by the YCRN, along with regular input and support from the YCRN Coordinating Centre staff. Throughout the development of the Network, we have given a high priority to providing practical help (eg administrative and educational) for the pre-existing clinical research support staff, as well as integrating the new YCRN staff into the existing framework.

## Outstanding Vacancies

The YCRN has 1 outstanding vacancies:

- 1 w.t.e. Research Nurse, Mid Yorkshire NHS Trust. To be appointed in June 2005.
- 1 w.t.e. Trial Coordinator, Lung, Network Wide, YCRN Coordinating Centre, To be appointed in August 2005.

### **Future Appointments**

The YCRN Executive regularly reviews the need for additional posts. Last year's annual report identified the need, as a direct result of the implementation of the EU Directive in May 2004, for an additional administrator to act as a Regulatory Officer, supporting the existing administrator and portfolio coordinators. During the set up period of this post, regulatory administrative work across the Network started to show signs of a slow down. Consequently this post was put on hold. The need for this post is currently under review.

### **Changes to the Staffing Profile**

7.1 wte, accounting for 9 individuals all actively recruit into a wide range of studies across the Network and are currently funded from non-recurring monies. The bulk of this funding ends during 2005. The YCRN will be in a position to fund up to 3 of these posts from its core budget. The YCRN, in conjunction with all existing employers, will explore alternative sources of funding but as things stand 6 of the posts will not be funded. This will result in a stop to recruitment in those areas and a downturn in YCRN recruitment.

## **1.2 Training and Development**

We appointed an Education and Information Manager in May 2004. Since then, training and development for YCRN staff has been raised to a new level. Training and career development are a high priority. The YCRN sees the investment in the role of Education Manager as important and worthwhile as this helps build a research infrastructure of well trained staff. Training and Development has progressed in two ways. Firstly, by the implementation of the NCRN Training and Education Standard Operating Procedure (see 1.2.2), and secondly, through the development of the YCRN education programme (see 1.2.3). Additional input for training has been provided by the Clinical Trials and Research Unit (CTRU) and the School of Healthcare Studies, both of the University of Leeds, and by the Institute of Clinical Research.

### **1.2.1 Induction**

The YCRN supports an induction programme tailored to the needs of the individual.

Research Nurse: Newly appointed research nurses are placed within a clearly defined management structure. An induction timetable is planned by the line manager of the new member of staff. This timetable, which is supported by the Education and Information Manager, is planned in advance and covers the initial 2-3 weeks. The induction timetable would include the following learning opportunities:

- ICH-GCP/ EU Directive update
- Working with experienced research nurses

- Spending time with data managers and trial coordinators
- Attending relevant clinics, MDT's and network meetings
- Meeting R&D and ethics committee departments
- Having an introduction to clinical trial SOP's
- Reviewing computer skills
- Meeting relevant medical staff

Data Managers and Trial Coordinators: Data managers and trial coordinators are allocated a mentor, and are provided with opportunities for networking with other disciplines within the research community. Most data managers are given an induction timetable that incorporates the above points. Access to external staff and agencies, such as the Cancer Services Collaborative and the Clinical Trials and Research Unit is also included in the induction of a new member of staff. All new members of staff are invited to spend some time at the YCRN base at Cookridge in order that they develop an understanding of the role of the YCRN within the service network.

### **1.2.2 Training and Education SOP**

The YCRN has played an active role in the revision of the original NCRN Training and Education SOP "Performing and documenting clinical team training". Although the newly revised SOP is not due to come into effect until 1<sup>st</sup> July 2005, the revised version has already been implemented throughout the network, which each funded member of the YCRN having carried out a training needs analysis with the Network Training Link.

### **1.2.3 Local Training**

The YCRN has developed a comprehensive training programme based on the needs of the network staff, as expressed in an audit of training needs carried out in June 2004. This programme includes a variety of subjects including:

- Regulatory requirements
- Trial design
- Data handling and CRF design
- Recruitment
- Consumer involvement
- Quality of life issues
- Audit preparation

This programme has incorporated local expertise as well as support from both the School of Healthcare Studies at the University of Leeds and the CTRU, also based at the University. The programme currently runs as a monthly series of sessions, lasting 2 hours. A review of this programme is now taking place in a response to an ongoing evaluation process. Feedback from all the sessions has been very good and suggests that the YCRN continues to address the educational needs of the staff.

The programme is constantly under review. It is important that the YCRN responds to changing needs. Following programme evaluation changes will be made e.g. length and format of future sessions.

Two study days have already taken place (Haematology study day and Consumers in Research study day). Both days were well attended and well received. A further

study day on Valid Informed Consent will take place in July. This has proved a popular session and has reached its capacity of 80 delegates less than 2 weeks after distributing the first advert.

The YCRN Education programme has been greatly assisted by the YCRN Update (a fortnightly email bulletin) and the Website (see 1.2.5), both of which have highlighted the profile of the planned educational events.

The YCRN educational programme has further developed links with the Institute of Clinical Research (ICR). As a result, 19 members of YCRN staff are now full members of the ICR. Membership entitles the individual to receive regular updates from the ICR, provide academic support, learning opportunities and further professional development within the field of research. The YCRN now hope to develop a “Northern Forum” of the ICR, accessible to all affiliated members, which will help deliver a series of further educational events relevant to practice, to complement the existing education programme.

#### **1.2.4 Attendance on NCRN and Local Training Courses**

See appendix 1.2.1 and 1.2.2

#### **1.2.5 Other Network Training and Development Initiatives**

ICH-GCP Training: To date the YCRN has registered 100 individuals who have received either local or national ICH – GCP training. The YCRN continues to provide ICH-GCP training for all staff throughout the network. A further study day is planned, aimed solely at pharmacists. This day will also be accessible to pharmacists working in the neighbouring Networks, as well as those working within our Network.

Communication course: The YCRN has successfully completed the first run of the “Communicating Randomised Clinical Trials” course by Professor Leslie Fallowfield. Each series of 4 modules, which form the complete course, can accommodate 10 individuals. The course will continue to run through the next year both in the YCRN and across the North of England see section 5.

Information: The YCRN has been creative in it’s dissemination of information to further training and development over the past year. This is evident in a number of ways:

The YCRN Website. The website receives an average of 10,725 hits per month. The website contains discussion forums, the latest information on trial portfolios and trial accrual, as well as a news and events section. This section highlights the training and education programme. Booking forms and further information on all the courses is available on line.

Consumer Web site. See point 4.

RCN Update. The YCRN promotes and circulates the RCN electronic update to all RCN members of the Research Team on a weekly basis. The RCN update circulates documents, calls for papers, promotes research finding and training, employment opportunities, disseminates the latest publications and informs members of future study days.

YCRN Information leaflet. The YCRN has composed an information leaflet aimed at clinicians and patients alike. This leaflet gives a brief outline of the work of the YCRN and an explanation of the key elements of taking part in a clinical trial. It lists some useful contacts and web site addresses, and invites the reader to contact the YCRN with any questions they may have in relation to research or clinical trials. This leaflet has been circulated to local hospital waiting areas and out patient clinics.

Journal Club. The YCRN is in the process of establishing a Journal Club with the first meeting planned for June 2005. It is open to all members of the research team. The aim of the Journal Club is to give all members the chance to meet and discuss the latest articles relevant to their practice in research.

YCRN Poster. The YCRN is submitting a poster for displayed at the NCRI Cancer Conference held in Birmingham in October 2005. The poster is entitled: "Promoting Excellence and Communication in Research within the Yorkshire Cancer Research Network." The aim of the poster is to promote the profile of the network and to share our structure and vision with others.

### **1.3 Structures and Integration**

The Research Networks management and reporting structures have changed over the last 12 months. This has happened in line with plans detailed in last year's annual report. The YCRN Executive has been extended; it now includes 15 individuals, representative of both the local and wider research community. The remit of this group is to provide direction for YCRN strategy. The YCRN Management Board, which represented the wider research community, had a remit to approve major strategic policy and funding decisions. This group has been discontinued. Their role has now been taken on by the YCN Management Board, providing an even closer working relationship with the service Network.

#### **Service Network**

The YCRN has a close working relationship with its service Network, the Yorkshire Cancer Network (YCN). Both the Lead Clinician and General Manager of the YCN sit on the YCRN Management Executive. The YCRN clinical lead sits on, and provides regular reports for, the YCN Management Board.

The YCRN has a presence at all the Network Tumour Groups. These meetings are primarily used to feedback information about the National / Local trials portfolios; this includes trial accrual, promoting new trials and discussing common issues. Three of the tumour groups have research subgroups; these are breast, gynaecology and urology. All are now established groups that discuss the issues raised above but in greater depth. They also have a focus on the development of local research ideas.

In addition to the Network Tumour Groups the YCRN links into the generic service network groups such as Cancer Drug Therapy, Imaging & Radiology and Histopathology. These services are crucial to the success of clinical trials and the Network Groups provide a welcome single forum for ensuring service support when initiating new trials.

#### **Network Hospitals and Staff**

The YCN comprises a single comprehensive Cancer Centre based within the Leeds Teaching Hospitals Trust (on 3 main hospital sites) plus six Cancer Unit Hospital Trusts (on 10 main hospital sites). Leeds Cancer Centre and Bradford Royal Infirmary are also jointly host to an NTRAC Centre and to the Cancer Research UK Clinical Centre in Leeds. These bring considerable clinical and laboratory expertise and resources, which enhance the clinical trials activity for the Network as a whole.

The Cancer Units have defined referral pathways for each cancer type, and some have designated Centre status for intermediate cancers (eg Upper GI and Urology), in accordance with the Improving Outcomes Guidance. All referrals for radiotherapy are made to the Cancer Centre, along with some of the intermediate cancer and all rare cancer referrals.

The Clinical Trial Coordinators are providing a vital link in identifying and improving pathways for clinical trial activity. These pathways and improved lines of communication enhance and speed up both staff working lives and patient journey times.

Communication across such a large Network is vital. All of the YCRN Coordinating Centre Staff visit all active units regularly, offering support and advice as well as acting as communication channels. Within the YCRN Coordinating Centre there is a weekly team brief which allows information to be shared about individual units; this ensures that relevant information is fed to the units and allows information return to the YCRN. The YCRN has taken this one step further and has a quarterly meeting to discuss individual unit's performance. The pilot of these meetings was successful in that it allowed the YCRN to ascertain and consider each Unit's strengths and areas for development.

### **Multidisciplinary Team (MDT) Meetings**

The MDT Meetings are perhaps the best forum for raising awareness of trials and identifying patients suitable for trial recruitment. There are approximately 80 MDT Meetings across the Network; this is in excess of 100 hours of MDT Meetings per week. It is unrealistic to expect every MDT Meeting to be attended by Research Nurses and Data Managers but they do attend MDT Meetings where they feel they can effectively contribute.

Standards at MDT Meetings continue increasing with the commitment of the YCN to MDT Coordinator training and development.

## **2. Accrual**

Dating from the establishment of the YCRN in 2001 there has been a year on year increase from 611 in 2001/02 to 1653 in 2004/05.

16.5% of newly incident cancer patients entered into NCRN portfolio studies in 2004/05. We are confident that the YCRN has helped achieve the national goal of 10%.

### **2.1 Overall Accrual into NCRN Studies**

In the period April 04 – March 05, the Network saw an increase of 127 patients who were entered into NCRN portfolio studies compared with the previous year. Despite the effects of the EU Directive the Network still managed to recruit 16.5%. This is slightly higher than the forecast made in last year's annual report, where it was anticipated that recruitment would level out at between 12 and 15%. However, there has been a slow down in the recent increases seen in recruitment. This is reflected at many Acute Hospital Trusts across the Network where recruitment has either stabilised or fallen over the last 12 months. Leeds and York have bucked this trend by delivering increases in recruitment of 9% and 155% respectively. Most of the disease sites recruitment have also levelled out although modest increases have been seen in colorectal, upper GI and urology, and in particular bladder and prostate trials.

Appendix 2.1

### **2.2 Accrual by Cancer Site into NCRN Portfolio Studies.**

The psychosocial and breast portfolios continue to be the biggest recruiters with 323 and 314 accrued respectively. This is a 15% increase in the psychosocial portfolio over last year whilst the breast portfolio has stabilised, even though in that period, several large national trials have closed to recruitment. Many large national trials have also closed in the colorectal, haematology and melanoma portfolios. These trials have not been immediately replaced by new trials, leaving a significant dent in each of those portfolios. Despite this however the colorectal portfolio has seen a Network wide recruitment increase of 23%.

Appendix 2.2 Accrual by Cancer Site into NCRN Portfolio Studies shows a detailed breakdown of recruitment by disease site.

### **2.3 Quarterly Accrual into NCRN Portfolio of Studies**

Appendix 2.3 shows quarterly recruitment from April 2002 – March 2005 (36 months). The graph depicts a typical pattern of recruitment taking into consideration seasonal variations. Throughout, there has been a steady increase in recruitment up to the second quarter of 2004/05. As already mentioned, this is due to several large trials closing to recruitment in the breast, colorectal and haematology and melanoma portfolios.

Previous annual reports have made annual recruitment comparisons using mean monthly accrual. Network accrual has risen from 51 patients in 2001/02 to 137.5 patients in 2004/05. Further details of mean monthly accrual for the Network and its individual hospitals can be found in table 1.

	2001/02	2002/03	2003/04	2004/05
Leeds Cancer Centre	314	466	846	1018
Airedale NHS Trust	58	90	191	58
Bradford Hospitals NHS Foundation Trust	62	69	82	106
Calderdale & Huddersfield NHS Trust	55	55	123	86
Harrogate and District NHS Foundation Trust	19	8	64	39
Mid Yorkshire Hospitals NHS Trust	78	111	158	175
York Health Services NHS Trust	25	27	66	173
Network	611	826	1530	1655

*Table 1. Total accrual by Trust, Years 1-4.*

## **2.4 Quarterly Accrual into NCRN Portfolio Studies by Hospital trusts.**

The Leeds Teaching Hospitals NHS Trust (Cancer Centre) has in previous years been responsible for just over half of the Networks recruitment, 54% in 2003/04. This has increased during the last year. The Cancer Centre was responsible for 61.5% of the Networks recruitment. One of the main reasons for this change is the effect that previously mentioned reductions in the NCRIs portfolios has had in the Cancer Units coupled with increasing recruitment in the intermediate and rare cancer portfolios at the Cancer Centre. The portfolio continues to strengthen across the whole range of cancers.

Credit for this activity also needs to be given to all hospitals within the Network as the recruitment total for this Trust includes inward referrals from all units. Inward referrals are mainly for trials involving rare or intermediate cancers, trials including radiotherapy or complex therapy trials not suitable for the Cancer Units. Current NCRN accrual data relate to the hospital of randomisation/registration, which is sometimes different from where the referral originated, or where the treatment takes place.

Airedale NHS Trust has a broad portfolio containing breast, colorectal, lung, gynaecology, haematology, upper GI and melanoma trials. The main strength continues to be the breast and colorectal portfolios although this year both have seen slow recruitment due to the closure of several large adjuvant trials. This year's recruitment stands at 58. Last year's peak of 191 was partly because of a locally adopted study of the effect of accessibility to cancer services from rural areas, which recruited 117 patients.

Bradford Hospitals NHS Foundation Trust's main strengths are the common cancer sites of breast and colorectal, accounting for over 60% of their annual recruitment in 2004/05. Recruitment was also strong for lung, gynaecology and haematology.

Bradford continues to show a year on year increase in recruitment with a 20% increase from 2003/04 – 2004/05; that is 82 patients compared to 106.

Calderdale & Huddersfield NHS Trust The strongest portfolio in this Trust has always been breast and this continues, with it accounting for 61% of the Trusts recruitment. Remaining recruitment covers the colorectal, lung, gynaecology, upper GI and skin portfolios. Calderdale & Huddersfield has seen a reduction in their recruitment for 2004/05 for breast and colorectal portfolio as seen throughout the Network. Recruitment for 2004/05 stands at 86.

Harrogate and District NHS Foundation Trust continues to do well despite a decrease in this year's recruitment. The strong portfolios are breast and lung, accounting for 75% of their total recruitment. Harrogate was affected by the closure of several large studies in the breast portfolio; the closure of GELCAPS in the lung portfolio also had a negative effect. Recruitment for 2004/05 stands at 39 patients compared with 64 patients for 2003/04.

Mid Yorkshire Hospitals NHS Trust comprises hospitals in Dewsbury, Wakefield and Pontefract. This Trust has particular strengths in haematological and urological research, with representation on NCRI CSGs for both. The Lead Clinician in haematology, a key driving force for haematology recruitment, has moved to the Cancer Centre but has left in place a robust research infrastructure which we hope will continue to thrive.

Recruitment continues to rise at Mid Yorkshire Hospitals with 175 patients entered in 2004/05 compared to 157 patients for 2003/04.

York Health Services NHS Trust has developed a strong portfolio in the common cancer sites. They recruit well into the breast and colorectal portfolios. This years accrual has been enhanced by a locally adopted study of the effect of accessibility to cancer services from rural areas, which recruited 84 patients; even without this, York have continued to add to their previous total. Recruitment this year stands at 173 patients compared with 66 patients for 2003/04.

## **2.5 Plans for Maintaining Accrual**

Last years forecast of maintaining recruitment between 12% and 15% of newly incident cancer patients remains the medium term goal for the YCRN. Despite recruitment of 16.5% this year, the YCRN is likely to see a slow down in recruitment. There are several reasons that will prevent the YCRN achieving higher recruitment over the coming 2 years. these are: lack of new trials to fill gaps left by trials that have closed, in particular the higher recruiting areas such as breast and colorectal; delays in opening trials to recruitment because of national and local regulatory and cost issues; staffing issues primarily at the Cancer Centre but also in the Cancer Units.

During the short term it is difficult to envisage recruitment above 15%; it is even likely that at 12% recruitment, quality of patient care and data returns could be compromised. The increasing number of patients in follow up, maintaining current recruitment and the reduction in research staff across the Network all contributes to future problems that will have a negative effect on recruitment. The YCRN funds approximately 25% of the Network's research staff; we are reliant on non-YCRN staff and the good will of clinicians to carry out much of the work. It is essential that we look at current working systems and develop novel ways in our approach to research.

Despite these restrictions there is still some work needed to improve recruitment in the common cancer sites, particularly lung, but the YCRN's shift in emphasis last year to support intermediate and rare cancers has started to show results. Increasing recruitment to these types of studies remains one of the key targets for the coming year.

### **3. Local Portfolio of NCRN Studies**

#### **3.1 Current NCRN Studies Portfolio**

The local portfolio continues to expand. It covers all the common, intermediate and rare cancers with the exception of head & neck.

#### **3.2 Local Trials Approval**

Three studies have been submitted for adoption this year. Two of those were approved. This makes a total of 13 studies submitted for either local or national adoption since the process was introduced.

#### **3.3 Strategy for Developing the Networks NCRN Portfolio**

The YCRN will continue to work with individual units, clinicians and groups wherever possible to develop the local portfolio. Research is on the agenda at most of the Tumour Groups and is gradually becoming a part of the generic Network Service Groups e.g. Cancer Drug Therapy and Imaging. Extra emphasis will be on the tumour groups this year, as new terms of reference are being introduced which will incorporate a wider research remit.

The common cancer site tumour groups are relatively well established and we will continue to support and develop them. However, the emphasis, as already stated in section 2.6, will be to increase activity in the intermediate and rarer cancers, such as gynaecology, head & neck, sarcoma, brain, upper GI, testis and bladder.

#### **3.4 Regulatory and Governance Issues**

As a large Network we have to liaise with several R&D departments and Ethics committees. Good relationships have been established and although we still experience some delays in approval, we are working closely to try and resolve problems that arise.

The implementation of the EU Directive has caused a lot of uncertainties and appears to have caused even more confusion in relation to research governance issues. The R&D Forum (see section 5) has enabled the YCRN to work closely with R&D departments ensuring good communication.

#### **4 Consumer involvement**

Consumer involvement has been a challenge. In September 2004, the YCRN established the "User Partnership Research Sub Group" to further develop the relationships between consumers and health care professionals, and to examine the many aspects of research today. The group initially organised a public event at the Civic Hall in Leeds, aimed at attracting a critical mass of people who wanted to explore the role of the consumer in the research process. Due to many set up problems this event had to be postponed.

A recent development is the YCRN is in the process of establishing a website for consumers. It is envisaged that this site would allow the YCRN to build a virtual community which would strengthen any work that consumers may wish to do as a group. The website would be accessible by users who wish to share information about events, articles, experiences or ideas with others. The website has the support of the service network who is promoting the initiative amongst their own consumers.

The User Partnership Research Sub Group continues to meet. There needs to be further clarity on the exact needs of research organisations like the YCRN and consumers in research. The YCRN will pursue this with the NCRN.

**5. Examples of Initiatives Developed in your Network that have been Particularly Effective**

- R&D Forum was set up to bring together the Network's R&D Managers. The group has met twice to date and productive discussions centre on complex and costly trials; training and education; governance and regulatory issues; R&D application / submission process. The group has improved relationships and communication across the Network. It is also looking at several cross Network projects.
- Professor Leslie Followfield's Communications Course is well recognised and is seen as important professional development for health care professional. The course requires trained facilitators to run a series of intense workshops; there are currently very few trainers. The YCRN is coordinating the provision of the Communications Course throughout seven of the Northern Cancer Networks. By sharing course facilitators and running the course at various venues throughout the Northern Networks, we hope to improve the availability and so attendance on the course by clinicians and research nurses in the north of England. Six complete courses have been planned to take place at various sites throughout the Northern Networks. This will ensure that a minimum of 60 delegates shall complete the communications course by March 2006. Discussion for further funding for this project is underway with various pharmaceutical companies.
- Relationship with CTRU. The Leeds University Clinical Trials and Research Unit is one of the NCRN accredited cancer trials units. From the start of YCRN we have had a formal relationship with this unit, accessing their expertise for education of our staff and support for new trial development within the Network Tumour Groups. Appendix 4 lists the results of the relationship.
- The YCRN Update is an electronic information update that is circulated to over 600 recipients every two weeks. This informs the research community of new trials, upcoming events, both locally and nationally, and disseminates any information related to research. The Update has been received well and is becoming a reputable forum for keeping the local research community up to date.

## 6. Future Plans and Work Plan for 2005/06

2004/05 has been mainly a year of consolidation but it has also had to adjust to several changes. The rapid increase in recruitment and regulatory changes presented many challenges over the year. Increased recruitment has highlighted the lack of research infrastructure and funding in service support departments. This has been one of the primary reasons for delays for new trials in the Network. New regulatory requirements have also made new trial development and trial set-up difficult; differing interpretation of regulation by individual R&D Departments has presented the YCRN Coordinating Centre Team with many difficulties.

This years plans are:

- The YCRN will continue to consolidate trial activity across the Network. This will include:
  - Working even closer with individual units to optimise trial set-up and recruitment. This includes a focus on all disease sites but with a particular emphasis on intermediate and rare cancers.
  - Working with the R&D Forum the YCRN will continue to push for a more streamlined approach to the R&D Application process.
  - The YCRN will highlight and will help seek solutions to issues raised in service departments such as pharmacy, radiology and pathology. This will be done in conjunction with Network Service Groups.
- The YCRN needs to respond to the changing needs in the Network. The role of the YCRN Trial Coordinators has been effective over the last 3 years, particularly in trial administration and coordination. Two Trial Coordinators have developed a more practical role in the Network, supporting trial recruitment and data collection. This has been well received and has boosted recruitment in upper GI and gynaecology. The YCRN plan to extend this concept to cover all disease areas with a particular focus on the intermediate and rare tumour portfolios. The YCRN will continue to provide its centralised Ethics and R&D application service.
- Education support and the Educational Programme have developed significantly over the last year, see section 1.2; this follows the appointment of the Education Manager. Education sessions are now longer. The YCRN has both half and full day sessions that target all research staff, the degree of success is evident in Appendix 1.2.2. The success and access to excellent conference facilities is enabling the YCRN to branch out in several ways:
  - The YCRN coordinates a Northern Training Alliance already demonstrated in section 5. One aspect of this alliance is the YCRN collating and advertising Educational Programmes for 7 Northern Networks. This allows access to all Northern Networks staff to any relevant education session across the North of England.
  - Part of the YCRN Education Programme includes generic, non-cancer specific, sessions. These include informed consent, audit process and a variety of regulatory sessions. In conjunction with the Network's R&D Departments these sessions are advertised to both cancer research and non-cancer research staff. The YCRN is positioning

itself to collaborate with new Networks as they evolve from the UKCRN to provide guidance and education sessions.

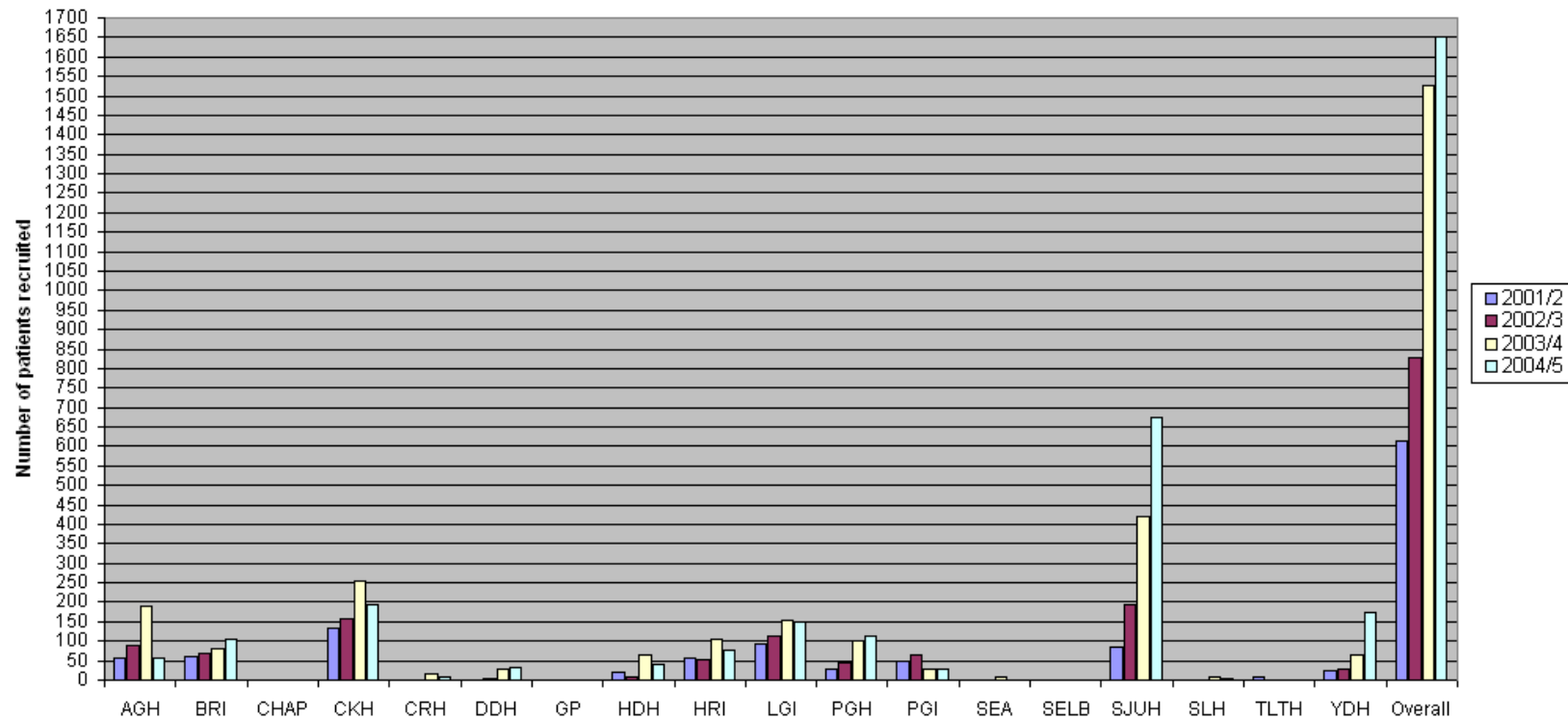
- A Flexible Trial Support grant from the YCRN will enable Mid Yorkshire Hospitals NHS Trust to look at lung cancer research across their hospitals. The grant will fund a part-time post that will help integrate research into the multi-disciplinary team. The aim is to recruit into a modest lung portfolio with minimal support for trial data collection by optimising the current skills of the Clinicians and Clinical Nurse Specialist.

## Appendices

## Appendix 2.1 - Overall accrual into NCRN Portfolio studies

	AGH	BRI	CHAP	CKH	CRH	DDH	GP	HDH	HRI	LGI	PGH	PGI	SEA	SELB	SJUH	SLH	TLTH	YDH	Overall
2001/2	58	62	0	132	0	2	0	19	55	91	30	48	0	0	84	0	7	25	613
2002/3	90	69	0	159	1	3	0	8	54	112	44	64	0	0	195	0	0	27	826
2003/4	191	79	0	255	16	30	0	64	107	155	100	27	10	1	418	7	0	66	1526
2004/5	58	103	0	193	9	31	0	39	77	148	114	30	0	0	675	3	0	173	1653

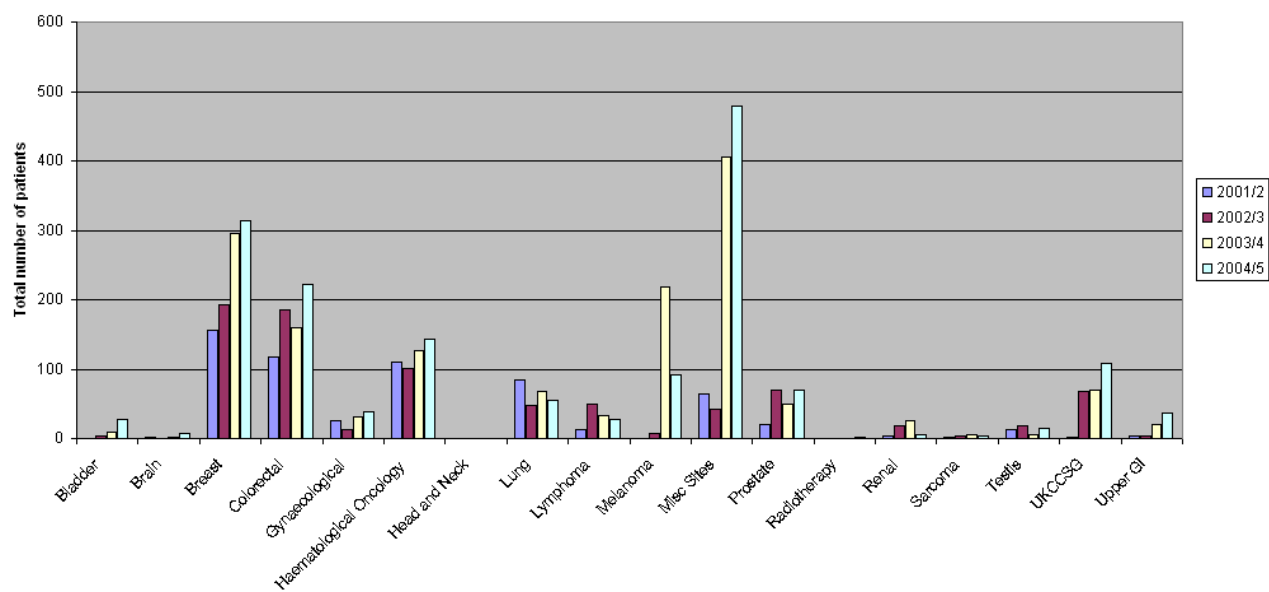
Annual Accrual for Yorkshire Cancer Research Network



## Appendix 2.2 - Accrual by cancer site into NCRN Portfolio studies

	Bladder	Brain	Breast	Colorectal	Gynaecological	Haematological Oncology	Head and Neck	Lung	Lymphoma	Melanoma	Misc Sites	Prostate	Radiotherapy	Renal	Sarcoma	Testis	UKCCSG	Upper GI
2001/2	0	1	156	117	25	111	0	85	13	0	64	20	0	3	2	12	1	3
2002/3	4	0	192	185	13	101	0	48	50	8	43	70	0	18	4	18	68	4
2003/4	10	2	295	160	32	126	0	68	33	219	50	0	26	5	5	70	70	20
2004/5	27	7	314	222	39	144	0	55	27	92	479	69	1	6	4	14	108	36

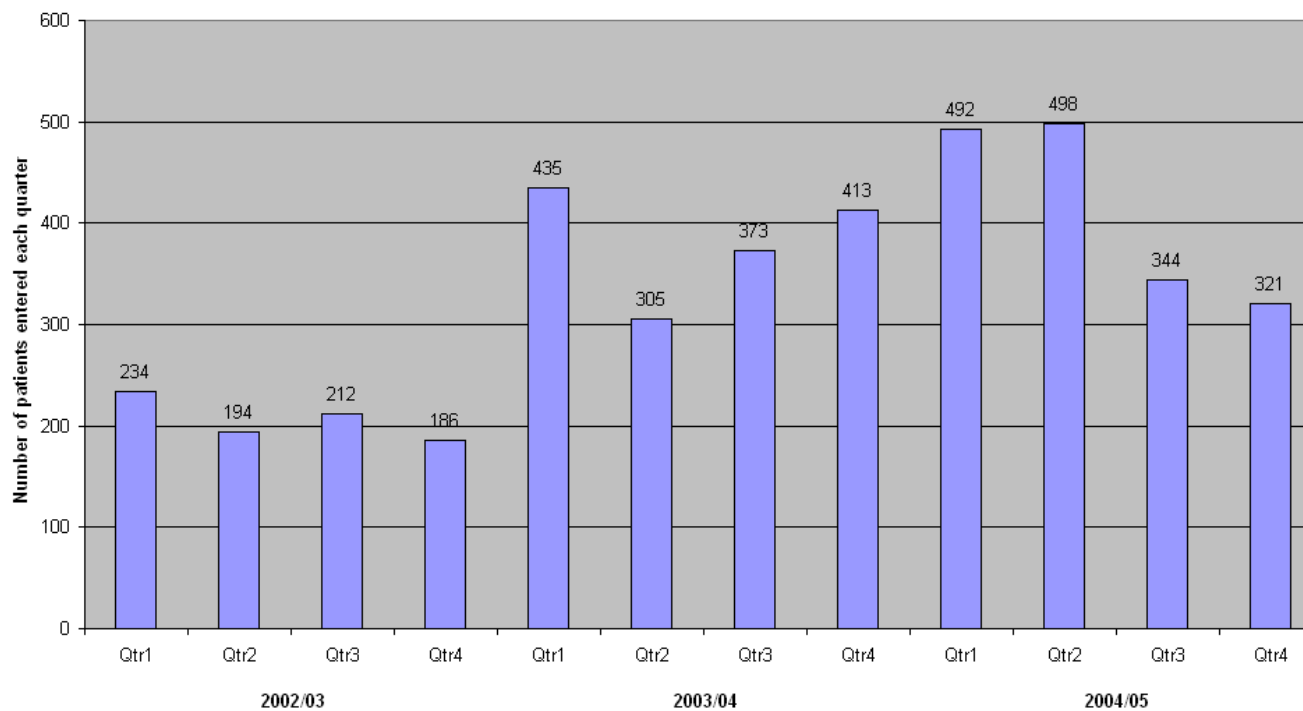
Annual Accrual by Cancer Site for Yorkshire Cancer Research Network



### Appendix 2.3 - Quarterly accrual into NCRN Portfolio studies for network

Qtr1	Qtr2	Qtr3	Qtr4	Qtr1	Qtr2	Qtr3	Qtr4	Qtr1	Qtr2	Qtr3	Qtr4
234	194	212	186	435	305	373	413	492	498	344	321

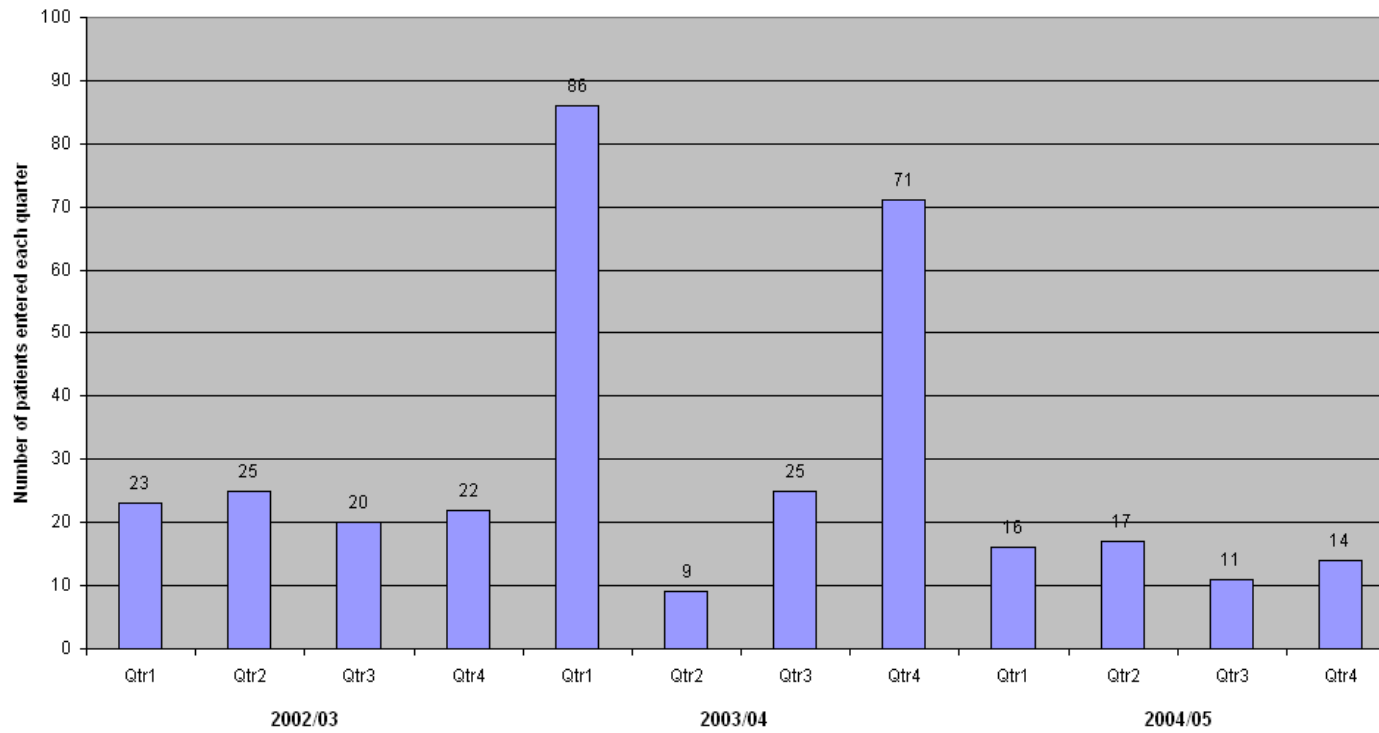
Quarterly Accrual for Yorkshire Cancer Research Network (Years 2 to 4)



## Appendix 2.4 - Quarterly accrual into NCRN Portfolio studies by trust

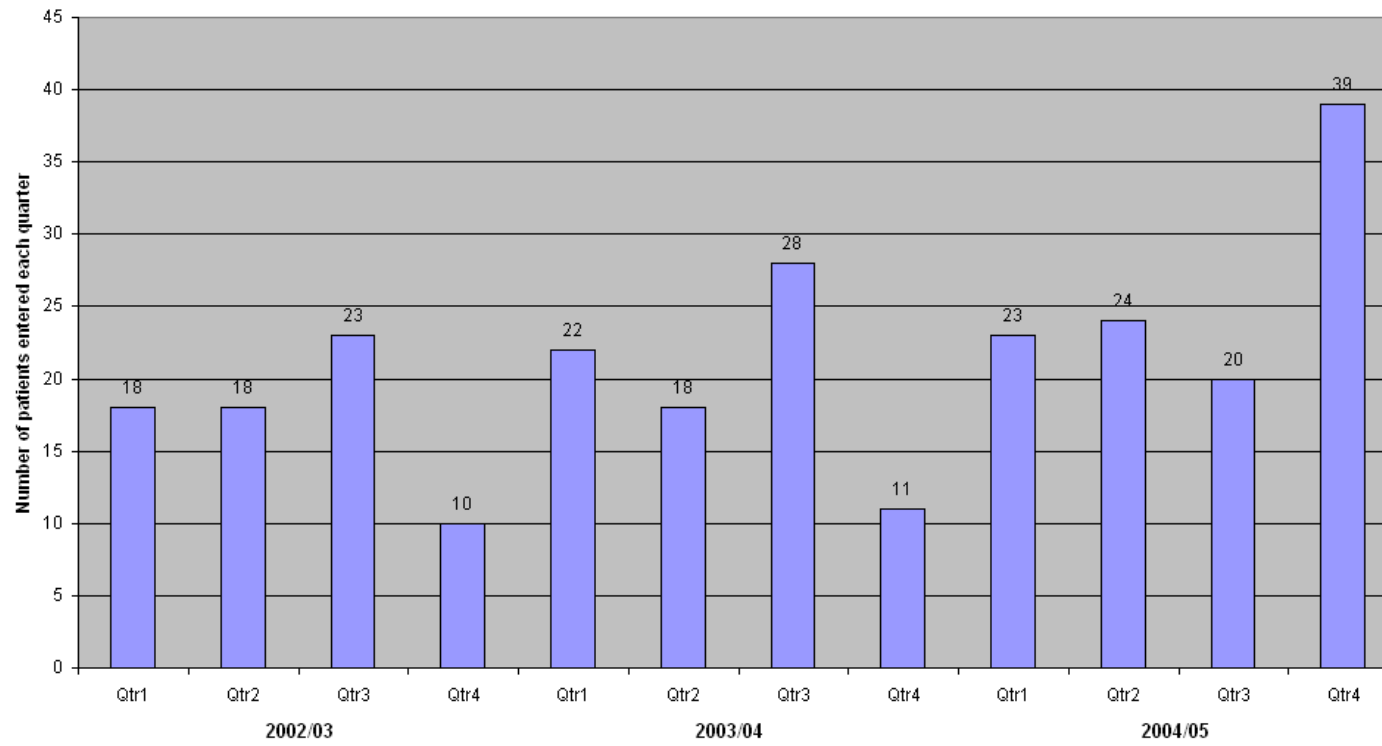
Qtr1	Qtr2	Qtr3	Qtr4	Qtr1	Qtr2	Qtr3	Qtr4	Qtr1	Qtr2	Qtr3	Qtr4
23	25	20	22	86	9	25	71	16	17	11	14

Quarterly Accrual for Airedale NHS Trust (Years 2 to 4)



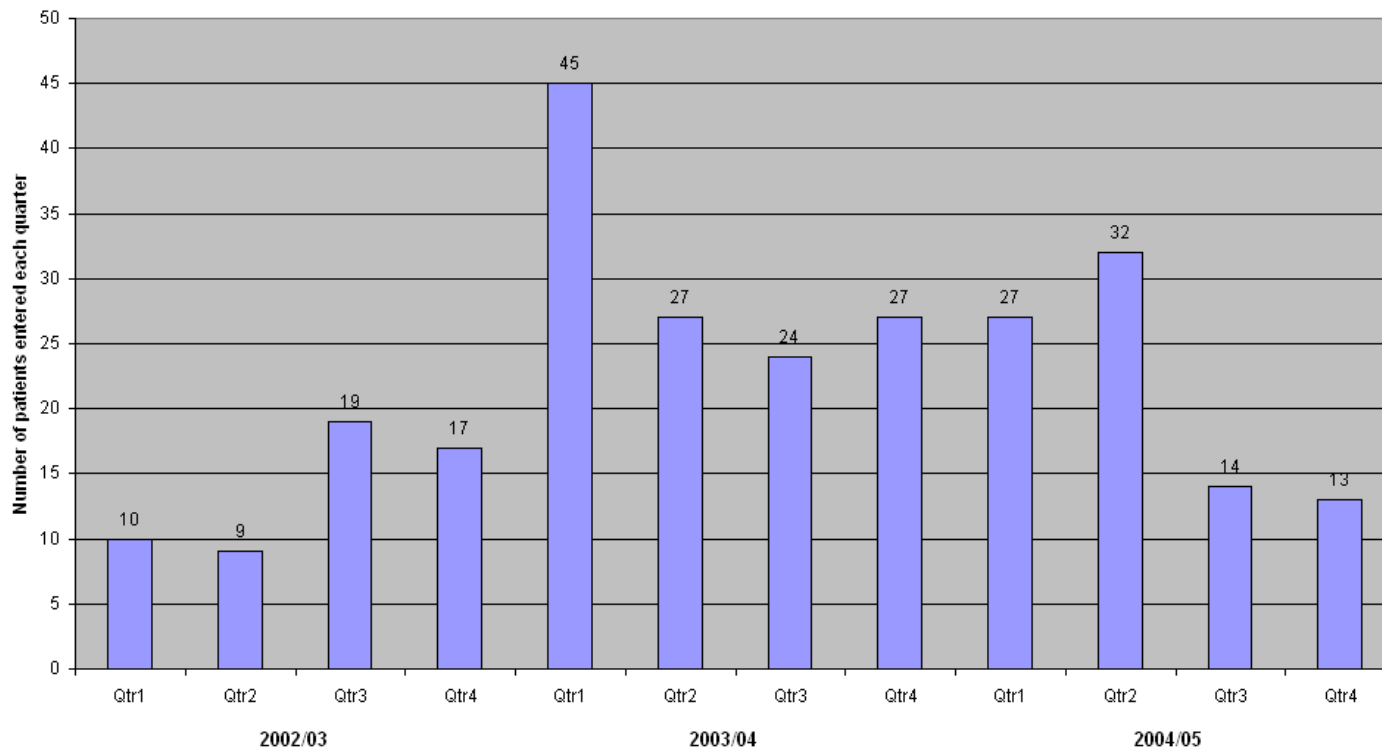
Qtr1	Qtr2	Qtr3	Qtr4	Qtr1	Qtr2	Qtr3	Qtr4	Qtr1	Qtr2	Qtr3	Qtr4
18	18	23	10	22	18	28	11	23	24	20	39

Quarterly Accrual for Bradford Teaching Hospitals NHS Foundation Trust (Years 2 to 4)



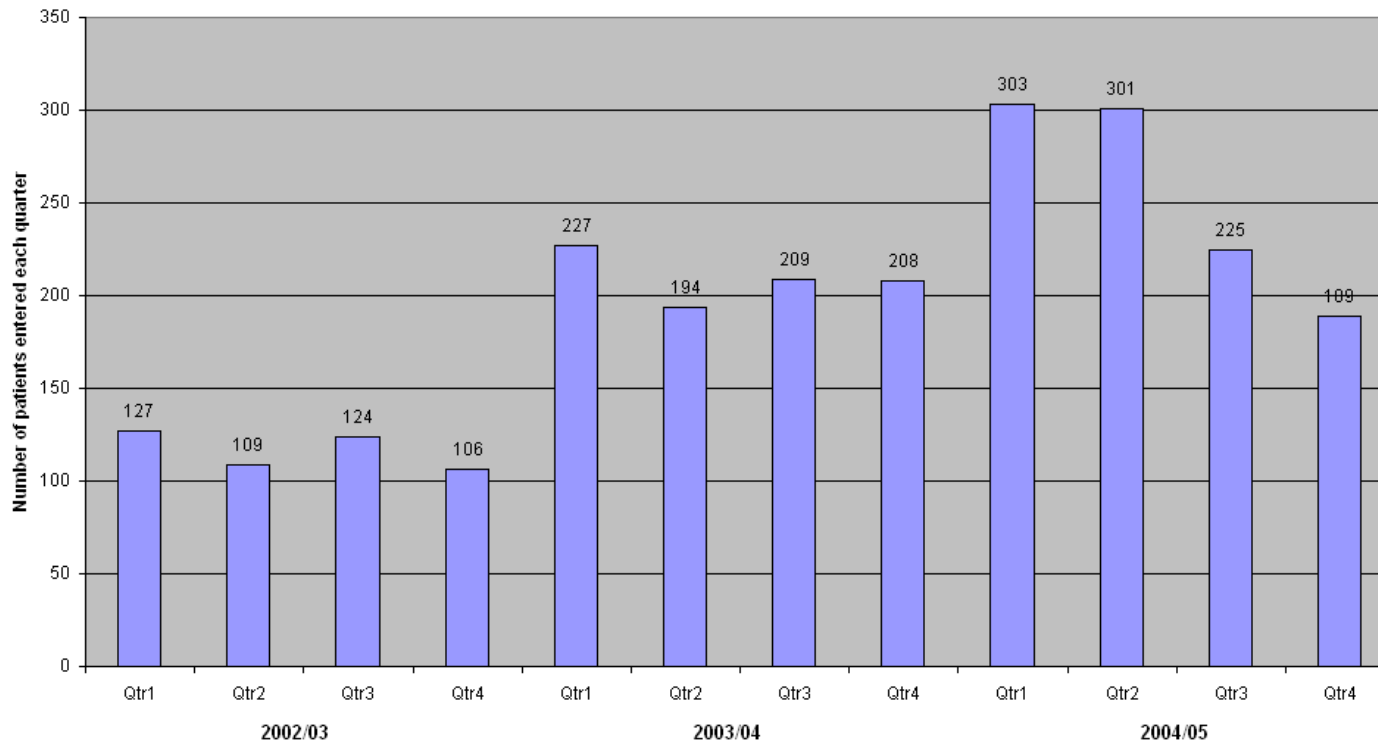
Qtr1	Qtr2	Qtr3	Qtr4	Qtr1	Qtr2	Qtr3	Qtr4	Qtr1	Qtr2	Qtr3	Qtr4
10	9	19	17	45	27	24	27	27	32	14	13

Quarterly Accrual for Calderdale & Huddersfield NHS Trust (Years 2 to 4)



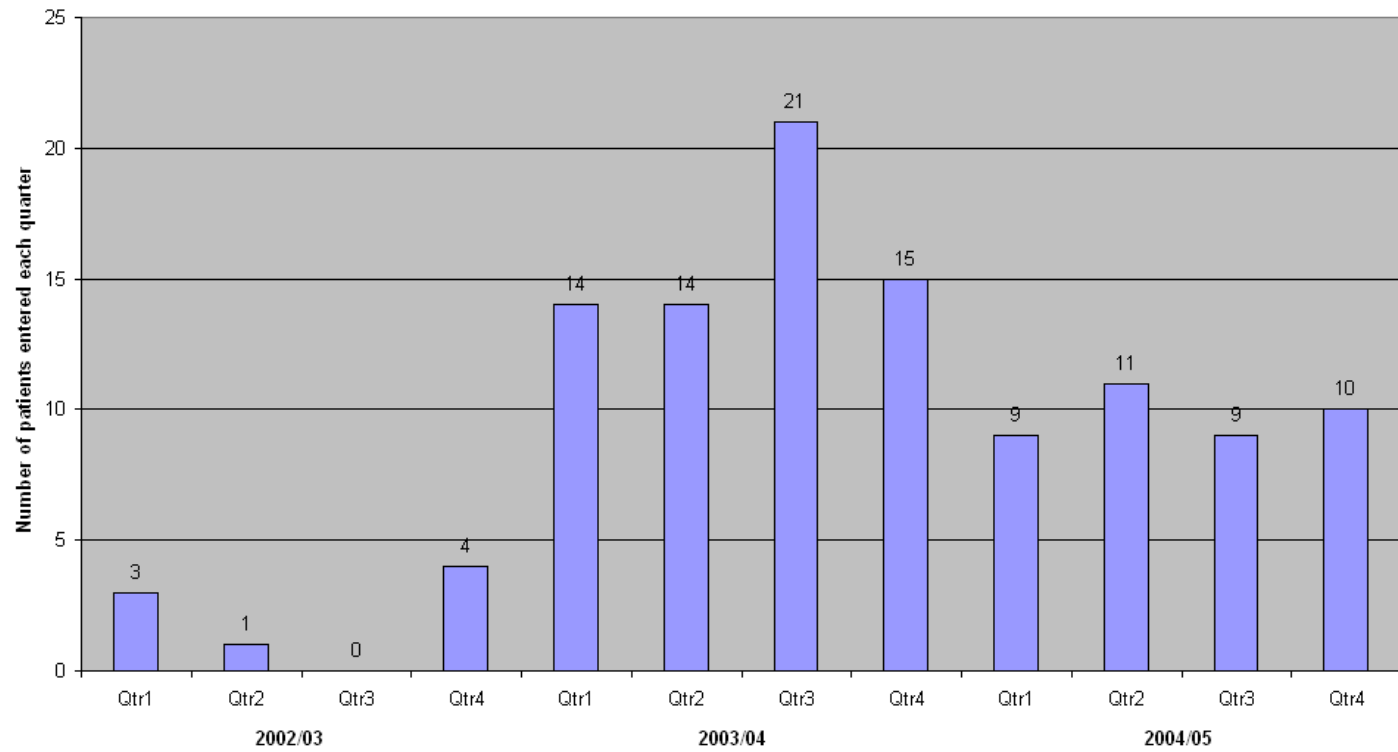
Qtr1	Qtr2	Qtr3	Qtr4	Qtr1	Qtr2	Qtr3	Qtr4	Qtr1	Qtr2	Qtr3	Qtr4
127	109	124	106	227	194	209	208	303	301	225	189

Quarterly Accrual for Leeds Teaching Hospitals NHS Trust (Years 2 to 4)



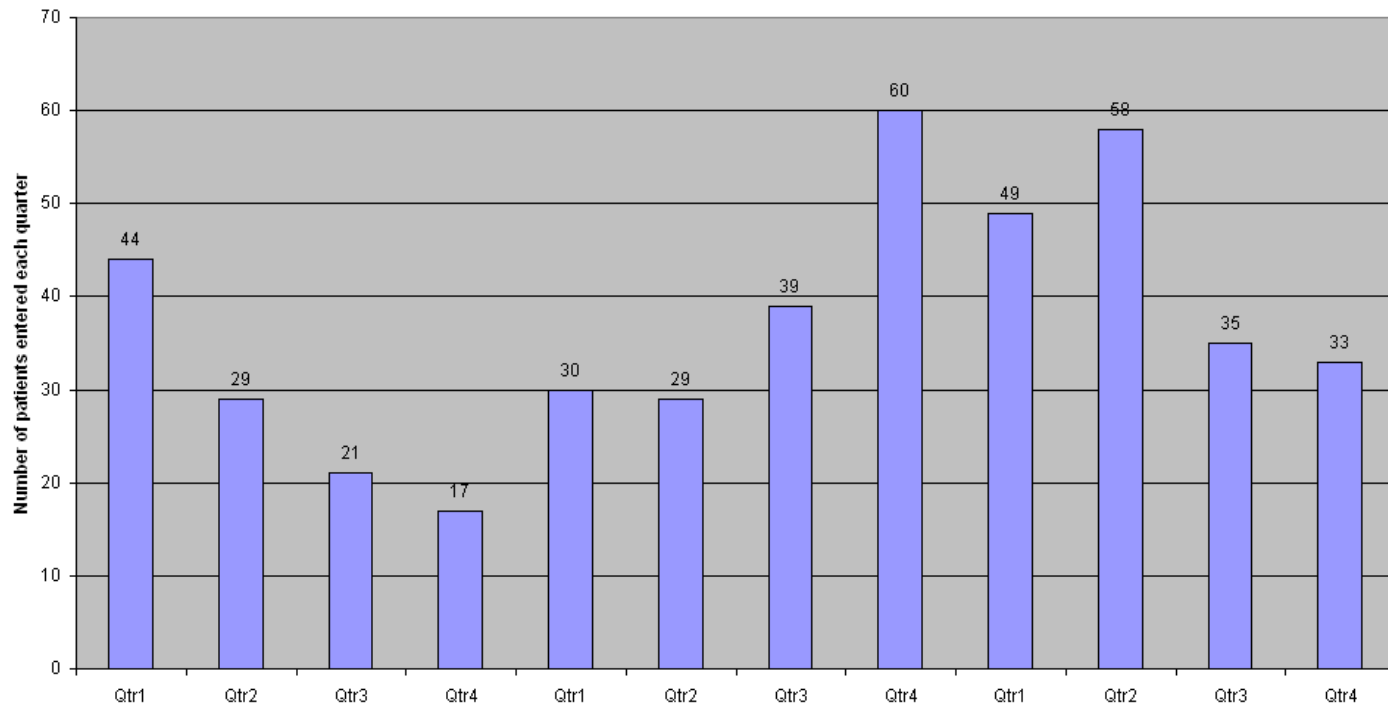
Qtr1	Qtr2	Qtr3	Qtr4	Qtr1	Qtr2	Qtr3	Qtr4	Qtr1	Qtr2	Qtr3	Qtr4
3	1	0	4	14	14	21	15	9	11	9	10

Quarterly Accrual for Harrogate & District NHS Foundation Trust (Years 2 to 4)



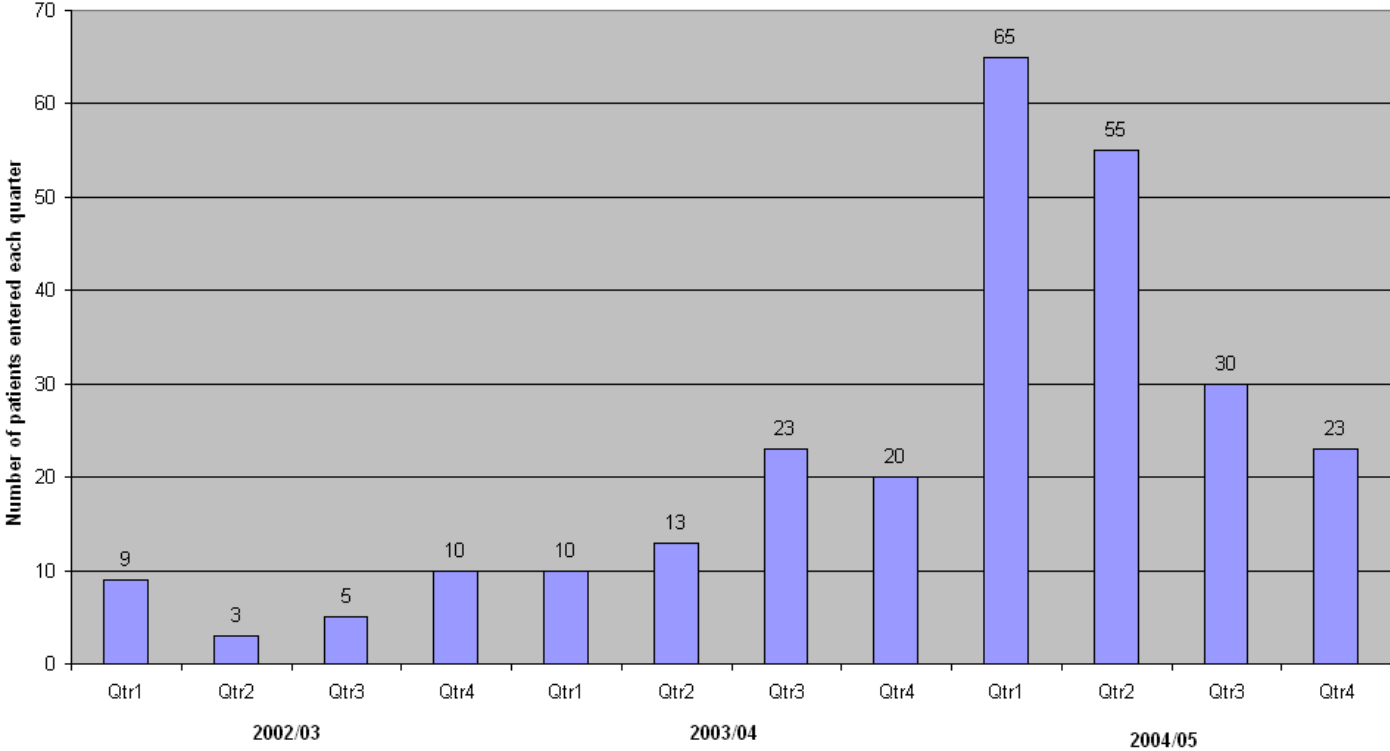
Qtr1	Qtr2	Qtr3	Qtr4	Qtr1	Qtr2	Qtr3	Qtr4	Qtr1	Qtr2	Qtr3	Qtr4
44	29	21	17	30	29	39	60	49	58	35	33

Quarterly Accrual for Mid Yorkshire Hospitals NHS Trust (Years 2 to 4)



Qtr1	Qtr2	Qtr3	Qtr4	Qtr1	Qtr2	Qtr3	Qtr4	Qtr1	Qtr2	Qtr3	Qtr4
9	3	5	10	10	13	23	20	65	55	30	23

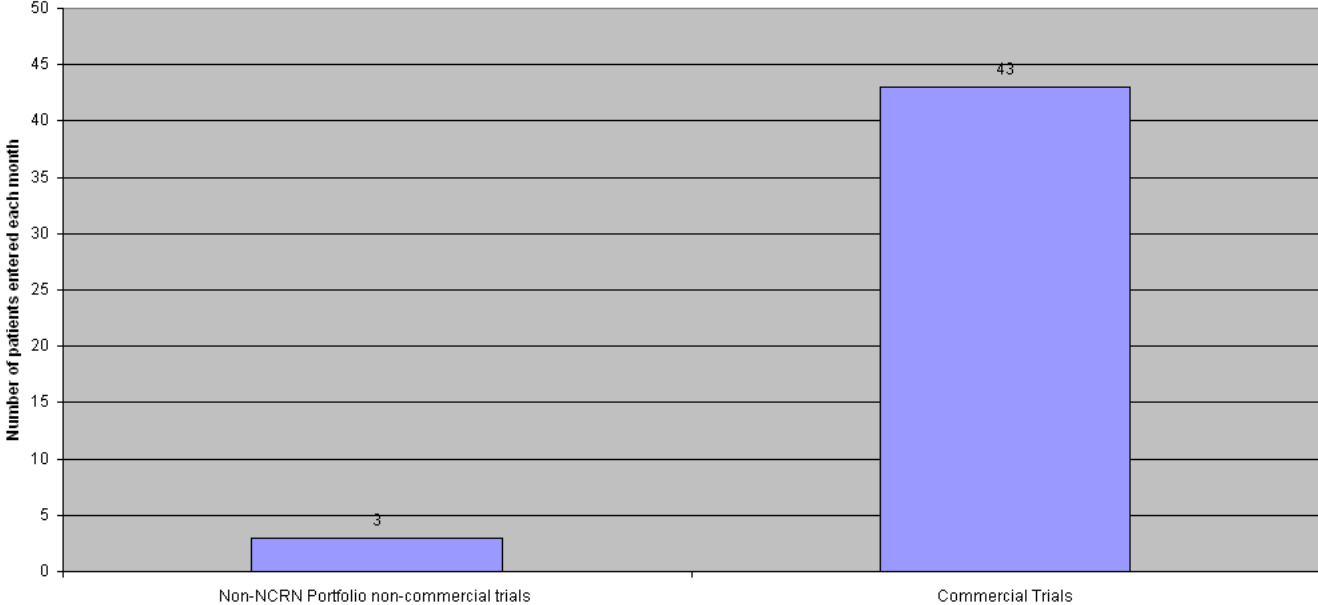
Quarterly Accrual for York Health Services NHS Trust (Years 2 to 4)



Appendix 2.5 - Accrual into Non-NCRN Portfolio studies

	Total
Non-NCRN Portfolio non-commercial trials	3
Commercial Trials	43

Accrual into Non-NCRN Portfolio Studies (Year 4) - Incomplete Data



**Appendix 4**  
**Clinical Trials and Research Unit, Leeds University.**  
**YCRN / CTRU Consultancy**

**Grant applications under development**

1. Pain Trial (Mike Bennett) - An investigation into the assessment and treatment of neuropathic pain in palliative care.

2. Gastric cancer (Dan Stark) - A randomised pilot study assessing capecitabine and capecitabine plus oxaliplatin in patients with inoperable or metastatic oesophago-gastric cancer, who are unsuitable for treatment with intensive combination therapy with ECF.

3. Social care intervention (Penny Wright) - Development of a complex intervention to assess and then support social care needs of cancer patients.

Outline Grant applications (awaiting result) – all to CTAAC

1. Choice (Geoff Hall) - A randomised phase II trial of sequential hormonal therapy and carboplatin-based chemotherapy for advanced/recurrent endometrial cancer

2. Oscar (Dan Stark) - A randomised phase III study to assess the Optimal Sequence of Chemotherapy At Relapse in patients with potentially platinum-sensitive epithelial ovarian cancer

3. ART (Peter Selby), invited for full application but postponed until August to allow pilot work to be conducted. A randomised feasibility adjuvant Autologous Renal carcinoma vaccine (ARCV) Trial comparing ARCV to ARCV /interleukin-2 to control (the ART trial)

4. UK CLL06 (Peter Hillmen) - A randomised phase III study in CLL to assess optimal chemotherapy regimens in patients with un-mutated and mutated disease.

**Outline Grant Applications (unsuccessful)**

1. Sarcoma (Mike Leahy) CTAAC - Randomised trial of escalation or discontinuation of Imatinib in patients with inoperable, locally advanced or metastatic Gastro-Intestinal Stromal Tumour (GIST) with progressive disease while on Imatinib.

2. Genetic epidemiology (Peter Selby) CRUK Population and Behavioural Sciences - A study of the relationship between genetic factors and the emotional response to cancer diagnosis

**Grant applications (successful)**

1. Piccolo - A randomised clinical trial of treatment for fluorouracil-resistant advanced colorectal cancer comparing standard single-agent irinotecan versus irinotecan plus panitumumab and versus irinotecan plus cyclosporin.

Considerable input from stats and trial co-ordination (no funding received yet).

Resubmitted to CTAAC x 2, TMG held, Intensive site visit from Amgen involving all Senior Staff (Programming, QA, TC, Stats).

2.Pact – NHS Trust, Stats and TC (for protocol review and randomisations) - (Patient Preferences in Adjuvant Colorectal Cancer Therapy) A randomised crossover clinical trial comparing Bolus Fluorouracil/Leucovorin to Capecitabine as treatment for moderate to high risk resected colorectal cancer.

**Additional presentations not charged as training;**

1.Sue Bell - HORN group (the YCRN's Haematological Oncology Research Network) – Clinical Trials in the Haematology portfolio

2.Su Mason – Informed consent (YCRN informed consent day)

Analysis consultancy

1. Das Gupta (liver resection qol)